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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,398	08/06/2003	David Anderson	21402-593C (CURA-893C)	1203
7590	07/12/2005		EXAMINER BORIN, MICHAEL L	
Jenell Lawson Intellectual Property CuraGen Corporation 555 Long Wharf Drive New Haven, CT 06551			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/635,398

Applicant(s)

ANDERSON ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20,21,23,26-28 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,21,23,26-28 and 36-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Status of Claims***

1. Examiner acknowledges amendment and response to restriction requirement filed 04/20/2005.

Applicants elected, without traverse, Group IX, claims 20-28,36-45. Further, applicant elected nucleic sequence SEQ ID No. 35. Claims 1-19,22,24,25,29-35,41-45 are canceled. Claims 20,21,23,26-28,36-40 are under examination.

### ***Priority***

2. It is brought to applicants' attention that for the purpose of examination, priority has not been granted to the claimed forty two provisional applications, for the elected invention because the Office has not been able to determine that the elected invention was disclosed in the claimed application due to the lack of disclosure of the elected sequences in the instant application. Applicant informs that the present invention is disclosed in provisional application 60/296404. However, applicant does not indicate what particular sequences in the provisional application correspond to the instant SEQ ID Nos. 35, 36. No CRF was filed with the provisional application to which priority is claimed. It is possible that the provisional application recites a sequence which is the same as instant SEQ ID NOs, but in the absence of a CRF for the application, the examiner has no way of determining whether any sequence recited in the provisional application is identical to instant SEQ ID Nos. Given the large number of sequences recited in the provisional application, and given the size of SEQ ID Nos. in the present

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case and each of the sequences recited in the provisional application, it would require undue effort on the part of the examiner to determine which, if any, of the sequences recited in the provisional application is identical to instant SEQ ID Nos. Applicant is invited to indicate what particular sequences in the provisional application correspond to the instant SEQ ID Nos. 35, 36.

***Information Disclosure Statement***

3. Applicants' Information Disclosure Statement filed 06/22/2005 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

***Claim Rejections - 35 USC 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim addresses "mature form of a polypeptide having sequence SEQ ID No. 36". The term "mature form" is not identified in the specification with respect to polypeptide SEQ ID No. 36. Consequently, it is not clear what

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polypeptides are addressed, and thus what polynucleotides encoding such polypeptides are encompassed by the claim.

***Claim Rejections - 35 U.S.C. § 101/ 112-1***

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 20,21,23,26-28,36-40 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The invention is drawn to isolated nucleic acids comprising sequence encoding polypeptide SEQ ID No. 36, nucleic acid comprising sequence SEQ ID No. 35, in particular. Utility of a polynucleotide is defined either by the utility of the polynucleotide itself or by utility of polypeptide it encodes. With respect to the utility of polynucleotide SEQ ID No. 35 itself, there is no indication of the utility of this particular polynucleotide. The data on pages 214-221 which applicant cites as providing evidence of utility, are directed to another gene, CG101826-02 which is related to SEQ ID No. 25 (SEQ ID No. 35 is related to CG101826-01). Insofar the claims address polynucleotides as

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encoding polypeptide SEQ ID No. 36, the utility of the polynucleotides is defined by the utility of the polypeptide they encode. Specification vaguely addresses polypeptide SEQ ID No. 36 as "adenylate kinase 5" (see Table A, p. 12); however, in the absence of particular information regarding the nature of the "adenylate kinase 5", this utility is not considered substantial as one skilled in the art would have to perform further experimentation to determine what the claimed product is useful for. Assignment to a prior art family of polypeptides is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the polypeptide family.

6. Claims 20,21,23,26-28,36-40 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial or a well-established utility for the reasons set forth above, one skilled in the art would not know how to make and/or use the claimed invention.

Further, in regard to claim 23, as the term "mature form" is not identified in the specification with respect to polypeptide SEQ ID No. 36, one skilled in the art would not know how to make the invention as claimed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb